TRANSLATED FROM RUSSIAN

RESEARCH OF THE MUTAGENIC ACTION

1. The mutagenic action of the material was studied in accordance with GOST R ISO 10993.10-99 “Medical devices. Study of biological action of medical devices. Part 3. Study of genotoxicity, carcinogenicity and toxic action on the reproductive function”.

The experimental animals were kept in accordance with GOST R ISO 10993.2-99 “Medical devices. Study of biological action of medical devices. Part 2. Regulations on protection of animals”.

Samples
The material is submitted is a sterile form. “ARGIFORM” is filled in disposable injection plastic syringes, which are tipped and vacuum-sealed in individual blister packaging. Each set consisting of a blister packaging with a syringe and an injection cannula which are packed into a separate branded carton box. The marking, description and the trademark are printed on the boxes.

2. Methods and results of the research

In experiment there was applied a method of evaluation of mutagenic activity on reticulocytes of femoral bone marrow of albino mice using a micronuclear test, which is a modified (accelerated) variant of method suggested by W. Schmidt in 1976.

3. Conclusion on the mutagenic activity

No mutagenic activity of the material was revealed during the micronuclear test on the preparations of bone marrow of albino mice.
The average cells amount with micronuclei comes to 3‰ and 4‰, at the permissible spontaneous value (reference) of 5‰ in the smears of the control and implanted animals.

The Leading researcher of Testing Laboratory
All-Russian Research and Testing institute of medical equipment
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